

UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Alderson *et al.*

Appl. No.: 09/499,468

Filed: February 7, 2000

For: **Use of Vascular Endothelial
Growth Factor to Treat
Photoreceptor Cells (as amended)**

Confirmation No.: 1320

Art Unit: 1647

Examiner: Landsman, Robert S.

Atty. Docket: 1488.100000F/HCC/PAC

**Fourteenth Supplemental Information Disclosure Statement
Filing Under 37 C.F.R. § 1.97(b)**

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fourteenth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Thirteenth Supplemental Information Disclosure Statement filed on January 27, 2006 in connection with the above-captioned application.

Copies of documents **FP3-FP13**, **NPL27-NPL65** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, documents **US5-US11**, cited on the attached Form PTO/SB/08A are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **FP4** and **FP5** cited on Form PTO/SB/08A:

Document **FP4**, JP 64-38100 A, is in the Japanese language. An English language abstract of document FP4 is attached as document **NPL33**.

Document **FP5**, JP 2-117698 A, is in the Japanese language. An English language abstract of document FP5 is attached as document **NPL34**.

Applicants would also like to bring to the attention of the Examiner that, for the following documents, the months of publication could not be determined to the best of the Applicants' ability: **NPL50**, Spranger, J. and Pfeiffer, A.F.H., "New concepts in pathogenesis and treatment of diabetic retinopathy," *Exp. Clin. Endocrinol. Diabetes* 109(Suppl. 2):S438-S450, J.A. Barth Verlag (2001); and **NPL51**, Stacker, S.A. and Achen, M.G., "The Vascular Endothelial Growth Factor Family: Signalling for Vascular Development," *Growth Factors* 17:1-11, Taylor & Francis (1999).

The listed documents became available to Applicants' undersigned representative on the following dates:

Document **NPL64** on February 17, 2006; and

Document **NPL65** on March 14, 2006.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Paul A. Calvo
Agent for Applicants
Registration No. 57,913

Date: April 26, 2006

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Substitute for form 1449/PTO FOURTEENTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/499,468
				Filing Date	February 7, 2000
				First Named Inventor	Ralph Alderson
				Art Unit	1647
				Examiner Name	Landsman, Robert S.
				Attorney Docket Number	1488.100000F/HCC/PAC
Sheet	1	of	2		

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² Number ² Kind Code ³ (if known)				
	FP3	EP 0 186 084 A2	07/02/1986	Merck & Co. Inc.		
	FP4	JP 64-38100 A	02/08/1989	Toray Ind. Inc.		Abs
	FP5	JP 2-117698 A	05/02/1990	Ajinomoto KK and Toray Ind. Inc.		Abs
	FP6	EP 0 399 816 A1	11/28/1990	Merck & Co. Inc.		
	FP7	WO 94/11506 A1	05/26/1994	Arch Development Corporation		
	FP8	WO 00/45835 A1	08/10/2000	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		
	FP9	WO 02/11769 A1	02/14/2002	Human Genome Sciences, Inc. and Coleman		
	FP10	WO 02/083704 A1	10/24/2002	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		

Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Sheet	2	of	2		

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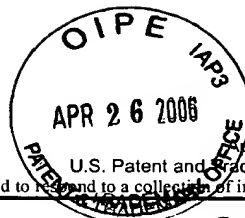
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Sheet	1	of	4	Attorney Docket Number	1488.100000F/HCC/PAC

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T ²
	NPL27	Borg, J.-P., <i>et al.</i> , "Biochemical characterization of two isoforms of FLT4, a VEGF receptor-related tyrosine kinase," <i>Oncogene</i> 10:973-984, Stockton Press (March 1995)	
	NPL28	Capogrossi, M.C., "Gene Therapy of Coronary Artery Disease," Project No. Z01 AG00811-01, Abstract (January 1994)	
	NPL29	Capogrossi, M.C., "Gene Therapy of Coronary Artery Disease," Project No. Z01 AG00811-02, Abstract (January 1995)	
	NPL30	Choi, I.H., <i>et al.</i> , "Angiogenesis and Mineralization During Distraction Osteogenesis," <i>J. Korean Med. Sci.</i> 17:435-447, The Korean Academy of Medical Sciences (August 2002)	
	NPL31	Copy of Declaration of Dr. Kari Alitalo, In re of: U.S. Application No. 08/585,895, Alitalo <i>et al.</i> , filed January 12, 1996, submitted November 26, 1997	
	NPL32	Dias, S., <i>et al.</i> , "Vascular endothelial growth factor (VEGF)-C signaling through FLT-4 (VEGFR-3) mediates leukemic cell proliferation, survival, and resistance to chemotherapy," <i>Blood</i> 99:2179-2184, The American Society of Hematology (March 2002)	
	NPL33	English language abstract of JP 64-38100 A, cited as document FP2 on Form PTO/SB/08A, Derwent Accession No. 1989-088700/198912	
	NPL34	English language abstract of JP 2-117698 A, cited as document FP3 on Form PTO/SB/08A, Derwent Accession No. 1990-181364/199024	
	NPL35	Fan, T.-P., <i>et al.</i> , "Controlling the vasculature: angiogenesis, anti-angiogenesis and vascular targeting of gene therapy," <i>Trends Pharmacol. Sci.</i> 16:57-66, Elsevier Science Ltd. (February 1995)	
	NPL36	Isner, J.M., <i>et al.</i> , "Arterial Gene Therapy for Therapeutic Angiogenesis in Patients With Peripheral Artery Disease," <i>Circulation</i> 91:2687-2692, American Heart Association, Inc. (June 1995)	

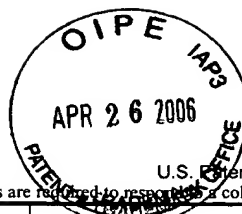
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				Examiner Name	Landsman, Robert S.
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NON PATENT LITERATURE DOCUMENTS				
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	NPL37	Isner, J.M. and Feldman, L.J., "Gene therapy for arterial disease," <i>Lancet</i> 344:1653-1654, The Lancet Ltd. (December 1994)		
	NPL38	Isner, J.M., <i>et al.</i> , "Physiologic Assessment of Angiogenesis by Arterial Gene Therapy with Vascular Endothelial Growth Factor," <i>J. Cell. Biochem. (Suppl. 21A)</i> :378, Abstract C6-215, Wiley-Liss (March-April 1995)		
	NPL39	Isner, J.M., "Therapeutic Angiogenesis in Vascular Medicine," Project No. R01 HL53354-01, Abstract (March 1995)		
	NPL40	Kubo, H., <i>et al.</i> , "Blockade of vascular endothelial growth factor receptor-3 signaling inhibits fibroblasts growth factor-2-induced lymphangiogenesis in mouse cornea," <i>Proc. Natl. Acad. Sci.</i> 99:8868-8873, The National Academy of Sciences (June 2002)		
	NPL41	Kuzuya, M. and Kinsella, J.L., "Induction of Endothelial Cell differentiation <i>in Vitro</i> by Fibroblast-Derived Soluble Factors," <i>Exp. Cell Res.</i> 215:310-318, Academic Press, Inc. (December 1994)		
	NPL42	Maher, P.A., "Stimulation of Endothelial Cell Proliferation by Vanadate Is Specific for Microvascular Endothelial Cells," <i>J. Cell. Physiol.</i> 151:549-554, Wiley-Liss, Inc. (1992)		
	NPL43	Mesri, E.A., <i>et al.</i> , "Expression of Vascular Endothelial Growth Factor From a Defective Herpes Simplex Virus Type 1 Amplicon Vector Induces Angiogenesis in Mice," <i>Circulation Res.</i> 76:161-167, American Heart Association, Inc. (February 1995)		
	NPL44	Mülhauser, J., <i>et al.</i> , "In Vivo Gene Transfer into Porcine Cardiac Cells with a Replication-Deficient Recombinant Adenovirus Vector," <i>Circulation</i> 88:I-475, Abstract No. 2558, American Heart Association (October 1993)		
	NPL45	Mülhauser, J., <i>et al.</i> , "VEGF ₁₆₅ Expressed by a Replication-Deficient Recombinant Adenovirus Vector Induces Angiogenesis In Vivo," <i>Circulation Res.</i> 77:1077-1086, American Heart Association, Inc (December 1995)		
	NPL46	Oikawa, T., <i>et al.</i> , "Three Isoforms of Platelet-Derived Growth Factors All Have the Capacity to Induce Angiogenesis <i>In Vivo</i> ," <i>Biol. Pharm. Bull.</i> 17:1686-1688, Pharmaceutical Society of Japan (December 1994)		

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Sheet	3	of	4	Attorney Docket Number	1488.100000F/HCC/PAC

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL47	Pajusola, K., <i>et al.</i> , "Signalling properties of FLT4, a proteolytically processed receptor tyrosine kinase related to two VEGF receptors," <i>Oncogene</i> 9:3545-3555, Stockton Press Ltd. (December 1994)	
	NPL48	Pepper, M.S., <i>et al.</i> , "In Vitro Angiogenic and Proteolytic Properties of Bovine Lymphatic Endothelial Cells," <i>Exp. Cell Res.</i> 210:298-305, Academic Press, Inc. (February 1994)	
	NPL49	Plate, K.H., "From angiogenesis to lymphangiogenesis," <i>Nat. Med.</i> 7:151-152, Nature America, Inc. (February 2001)	
	NPL50	Spranger, J. and Pfeiffer, A.F.H., "New concepts in pathogenesis and treatment of diabetic retinopathy," <i>Exp. Clin. Endocrinol. Diabetes</i> 109(Suppl. 2):S438-S450, J.A. Barth Verlag (2001)	
	NPL51	Stacker, S.A. and Achen, M.G., "The Vascular Endothelial Growth Factor Family: Signalling for Vascular Development," <i>Growth Factors</i> 17:1-11, Taylor & Francis (1999)	
	NPL52	Symes, J.F. and Sniderman, A.D., "Angiogenesis: potential therapy for ischaemic disease," <i>Curr. Opin. Lipidol.</i> 5:305-312, Current Science Ltd. (August 1994)	
	NPL53	Takeshita, S., <i>et al.</i> , "In Vivo Evidence of Enhanced Angiogenesis Following Direct Arterial Gene Transfer of the Plasmid Encoding Vascular Endothelial Growth Factor," <i>Circulation</i> 88:I-476, Abstract No. 2565, American Heart Association (October 1993)	
	NPL54	Takeshita, S., <i>et al.</i> , "Therapeutic Angiogenesis. A Single Intraarterial Bolus of Vascular Endothelial Growth Factor Augments Revascularization in a Rabbit Ischemic Hind Limb Model," <i>J. Clin. Invest.</i> 93:662-670, The American Society for Clinical Investigation, Inc. (February 1994)	
	NPL55	Walsh, D.A. and Pearson, C.I., "Angiogenesis in the pathogenesis of inflammatory joint and lung diseases," <i>Arthritis Res.</i> 3:147-153, BioMed Central Ltd. (February 2001)	
	NPL56	Williams, R.S., "Southwestern Internal Medicine Conference: Prospects for Gene Therapy of Ischemic Heart Disease," <i>Am. J. Med. Sci.</i> 306:129-136, Lippincott Williams & Wilkins (August 1993)	

Examiner Signature	Date Considered
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	NPL57	Witzenbichler, B., <i>et al.</i> , "Vascular Endothelial Growth Factor-C (VEGF-C/VEGF-2) Promotes Angiogenesis in the Setting of Tissue Ischemia," <i>Am. J. Pathol.</i> 153:381-394, American Society for Investigative Pathology, Inc. (August 1998)	
	NPL58	Yeung, P.K.F., "VEGF-2," <i>Curr. Opin. Invest. Drugs</i> 2:796-800, PharmaPress Ltd.(June 2001)	
	NPL59	Anderson, W.F., "Human gene therapy," <i>Nature</i> 392:25-30, Macmillan Magazines Ltd (April 1998)	
	NPL60	Maynard, J. and Georgiou, G., "Antibody Engineering," <i>Annu. Rev. Biomed. Eng.</i> 2:339-376, Annual Reviews (August 2000)	
	NPL61	Morea, V., <i>et al.</i> , "Antibody Modeling: Implications for Engineering and Design," <i>Methods</i> 20:267-279, Academic Press (March 2000)	
	NPL62	NCBI Entrez, Accession No. AF010302, Mandriota S.J. and Pepper, M.S. (07/16/1997)	
	NPL63	NCBI Entrez, Accession No. S08167, Paulsson, G. <i>et al.</i> (04/23/1993)	
	NPL64	Letter from John J. Chicca II, Ph.D., Molecular Diagnostic Services, Inc. regarding a third progress report for a project entitled "Cloning and expression of VEGF-2 gene and the efficacy of VEGF-2 protein utilizing the 3-D collagen angiogenesis assay and proliferation," dated February 16, 2006.	
	NPL65	Letter from John J. Chicca II, Ph.D., Molecular Diagnostic Services, Inc. regarding a fourth progress report for a project entitled "Cloning and expression of VEGF-2 gene and the efficacy of VEGF-2 protein utilizing the 3-D collagen angiogenesis assay and proliferation," dated March 14, 2006.	

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